



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re to the Application of: Ayad ABDUL-AHAD and Dietmar GROSS	Examiner: Not Yet Assigned
Serial No.: 10/815,342	Group Art Unit: Not Yet Assigned
Filed: 1 April 2004	
Title: Higher Doses Of Interferon- Beta For Treatment Of Multiple Sclerosis	
Docket No.: 53208AUSM1	

Office of Petitions and
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 CFR § 1.47
RE REFUSAL OF INVENTOR TO SIGN AN OATH OR DECLARATION

Dear Sir:

This Petition pursuant to 37 CFR § 1.47 is responsive to the Notice To File Missing Parts mailed 3 August 2004, in the above-referenced nonprovisional application and requests acceptance of the application where a joint inventor, Ayad Abdul-Ahad, refuses to sign the related declaration. Included in the response to the Notice is the Declaration of Dietmar Gross, who is the other joint inventor in the present application. The present application is made by Mr. Gross on behalf of himself and Mr. Abdul-Ahad.

Pursuant to the requirements of 37 CFR § 1.47, the following information is provided: 1) proof of pertinent facts showing that the filing of the application by Mr. Gross on behalf of the named inventors is necessary to preserve the rights of Applicant; 2) the last known address of Mr. Abdul-Ahad which is: 10 Birch Drive, Basking Ridge, New Jersey, 07920; and 3) proof that a copy of the application and related declaration form was sent to and received by Mr. Abdul-Ahad on 25 March 2004 via email. In addition, Applicant hereby authorizes the Commissioner to charge any fees associated with this Petition to Deposit Account No. 02-2117.

Refusal

Attorney for Applicant and signer of the present Petition (herein after referred to as "the present attorney"), conducted an investigation concerning the inventorship of the invention claimed in the present application and found that Mr. Gross and Mr. Abdul-Ahad are co-inventors of the claimed invention, pursuant to US law. Mr. Abdul-Ahad was informed of these findings by the present attorney. However, contrary to these findings, Mr. Abdul-Ahad claims that he is the sole inventor and refuses to sign the declaration form related to the present application, unless the form indicates that he is the sole inventor.

Application Serial No. 10/815,342
Attorney Docket No. 53208AUSM1
Petition Under 37 CFR 1.47

Documentary Evidence and Statement of Facts

Applicant hereby submits the requisite proof and statement of facts under 37 CFR § 1.47, including the attached email communications sent by Mr. Abdul-Ahad to the present attorney, and sent to and received by Mr. Abdul-Ahad by the present attorney. These communications provide documentary evidence that: 1) Mr. Abdul-Ahad was provided with and acknowledged receipt of a copy of the application and related declaration form for his review and signature, prior to the filing of the application; 2) Mr. Abdul-Ahad refused to sign this declaration form, unless he is indicated on the form as the sole inventor; and 3) the present attorney provided Mr. Abdul-Ahad with the copy of the application and declaration form, and is the person to whom Mr. Abdul-Ahad communicated his refusal to sign the declaration relating to the present application.

Applicant submits that prior to the filing of the present application 1 April 2004, Mr. Abdul-Ahad was provided by the present attorney with a copy of the application (along with figures and sequence listings), and declaration and assignments forms relating to the application. These documents were sent as attachments via email 25 March 2004, from the present attorney to Mr. Abdul-Ahad (see attached copy of email of 25 March 2004, 10:17 a.m.). Later that same day, the present attorney spoke to Mr. Abdul-Ahad via telephone concerning: 1) the documents that had been sent to him earlier that day; 2) the findings of the above-mentioned investigation that indicate that he is not the sole inventor and that Mr. Gross is a co-inventor; 3) his claim that he is the sole inventor; 4) his refusal to sign the declaration form, unless it indicates that he is the sole inventor; and 5) that in view of his claim to sole inventorship, the present attorney would conduct a follow-up investigation on inventorship of the claimed invention. A summary of the telephone conversation is provided in the email sent 30 March 2004 from the present attorney to Mr. Abdul-Ahad (see attached copy of email of 30 March 2004, 8:43 a.m.).¹ The email of 30 March 2004 is in reply to an email sent by Mr. Abdul-Ahad to the present attorney on 29 March 2004 in which he mischaracterizes the above-mentioned telephone conversation, and in which he acknowledges receipt of the application sent by the present attorney as an attachment in the above-mentioned email of 25 March 2004, along with the related oath/declaration (see attached copy of email of 29 March 2004, 6:19 p.m.). In reply to the above-mentioned email of 30 March 2004, Mr. Abdul-Ahad sent an email to the present attorney on the same day, reiterating his claim that he is the sole inventor and refusal (see attached copy of email of 30 March 2004, 8:52 a.m.).²

In addition to the above-mentioned email communications, prior to the filing of the present application, and in March 2004, Mr. Abdul-Ahad was contacted by the present attorney via telephone on several occasions to address any concerns of Mr. Abdul-Ahad relating to the application and, in particular, to provide clarification about, and to discuss in detail, inventorship of the invention claimed in the present application, the contents of the application particularly the claimed invention, and the declaration and assignment forms. Further, the present attorney conducted a follow-up investigation concerning inventorship, following Mr. Abdul-Ahad's assertion that he is the sole inventor and the

¹ The email of 30 March 2004 incorrectly indicates 24 March 2004 as the date of the telephone conversation which occurred on 25 March 2004.

² Mr. Abdul-Ahad sent and received the above-mentioned emails from the East Coast and the present attorney sent and received the above-mentioned emails from the West Coast and, thus, the differences in time stamps indicated on the emails reflect the time according to Eastern Standard Time and Pacific Standard Time, respectively.

Application Serial No. 10/815,342
Attorney Docket No. 53208AUSM1
Petition Under 37 CFR 1.47

findings of the investigation are consistent with the previous investigation concerning inventorship of the invention claimed in the present application, i.e., Mr. Abdul-Ahad is not the sole inventor and Mr. Gross is a joint inventor.

Conclusion

Applicant submits that the remarks herein, including the statement of facts and documentary evidence satisfy the requirements under §1.47 and respectfully request favorable consideration of this Petition for acceptance of the present application.

Respectfully submitted,

Date: 4 October 2004



Anna Gil, Reg. No. 46,726
Attorney for Applicants

BERLEX BIOSCIENCES
Corporate Patents
2600 Hilltop Drive
P.O. Box 4099
Richmond, CA 94804-0099

General Tel. No.: (510) 262-500
Direct Dial Tel. No.: (510) 669-4758
Fax. No.: (510) 262-7095

DECLARATION AND POWER OF ATTORNEY

Attorney Case No. 53208AUSM1



As a below named inventor, I hereby declare:

That my citizenship is as stated below next to my name;

That, I verily believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled:

HIGHER DOSES OF INTERFERON-BETA FOR TREATMENT OF MULTIPLE SCLEROSIS

described and claimed in the specification of United States patent application serial no. 10/815,342, that I have reviewed and understand the contents of the attached specification, including the claims, that I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application, that I acknowledge my duty to disclose information of which I am aware which is material to the examination of this application in accordance with 37 CFR §1.56(a), and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows:

None

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith:

Neil G. Miyamoto, Registration No. 50,370
Melissa A. Shaw, Registration No. 38,301
Wendy L. Washtien, Registration No. 36,301
Ronald S. Hermenau, Registration No. 34,620
Anthony J. Zelano, Registration No. 27,969
Anna Gil, Registration No. 46,726

Address all telephone calls to Anna Gil at telephone number (510) 669-4758

Address all correspondence to Anna Gil, Berlex Biosciences, Patent Department, 2600 Hilltop Drive, P.O. Box 4099, Richmond, California 94804-0099.

DECLARATION AND POWER OF ATTORNEY

Attorney Case No. 53208AUSM1

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

First Joint Inventor

Full name: Ayad Abdul-Ahad

Signature: _____

Date: _____, 2004

Citizenship: GB

Second Joint Inventor:

Full name: Dietmar Gross

Signature: Dietmar GrossDate: Sep 01, 2004

Citizenship: DE



Anna Gil

03/25/04 10:17 AM

Addressing

To: aabdulahad@optonline.net
cc: Mary Ann Flores/RM/USR/SHG@SCHERINGGROUP
Subject: Declaration and Assignment Forms, and 3-25-04 Revised Appln re Higher-Dose IFNB for Treatment of MS

Privileged and Confidential Attorney Work Product
(Please do not copy or forward.)

Dear Ayad,

My apologies for the delay in sending the application and Declaration and Assignment forms to you for your review and signing. I have been working continuously on this matter, and only just completed the revised version of the application.

Please find attached the Declaration and Assignment forms for your signature and the 3-25-04 revised version of the above-mentioned patent application. The figures are also attached and will be formatted and appropriately numbered before we file the application. Similarly, the amino acid sequence listing 1 (SEQ ID NO: 1) of a native IFNB and amino acid sequence listing 2 (SEQ ID NO: 2) of Betaseron will be attached and submitted with the application when we file.

Please note that it is important that you first read and understand the application before signing the Declaration and Assignment forms. After you have completed/signed the forms, please return the originals to Mary Ann Flores via overnight mail (if this is problematic, please let me know asap). Please also fax a copy of the completed forms to Mary Ann at (510) 262-7095.

Since this matter is of urgency, we would greatly appreciate the receipt of both the original and fax copy of the Declaration and Assignment forms (and any additional comments/revisions re the application) **no later than Monday, 29 March 2004.**

Also, if you could provide us with your contact information in Switzerland, we would greatly appreciate it.

Thank you very much for your help on this matter. I look forward to talking with you later today.

Best regards,
Anna

53208AUSM1 DECPOA xxMAR04.c 53208AUSM1 ASSIGN xxMAR04.d

3-25-04 VERSION (EX1) US UTL APPLN re HI-DOSE IFN 3-25-04 FIGS 1-4 re EX1 re HI-DOSE IFNB UTL APPI

3-25-04 FIGS 5-6 re EX1 re HI DOSE IFNB UTL APPI

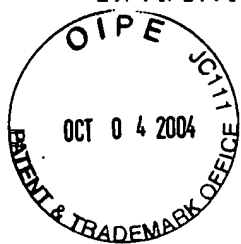
Anna Gil, Ph.D.
Senior Patent Attorney

BERLEX PHARMACEUTICALS
2600 Hilltop Drive
P.O. Box 4099

11/20

10/04/2004 MON 19:35 FAX 510 262 7095 Berlex Biosciences

012/020



Richmond, CA 94804-0099
USA

Tel. No.: (510) 669-4758
Fax. No.: (510) 262-7095
Web Site: Berlex.com

This email (and any accompanying attachments) contains information that may be confidential and privileged and is intended solely for the use of the intended recipient. Unless you are the intended recipient, please do not use, copy or disclose the contents of the email (and any accompanying attachments). If you have received this email (and any accompanying attachments) in error, please immediately notify Anna Gil at (510) 669-4758 or anna_gil@berlex.com and delete this email (and any accompanying attachments).

12/20



aabdulahad@optonline.net

03/29/04 06:19 PM

Addressing

To: Anna_Gil@berlex.com

cc: Mary_Ann_Flores@BERLEX.COM

Subject: Re: Revised Declaration and Assignment Forms re Appln re Higher-Dose IFNB for Treatment of MS

13/20



Dear Anna,

Sorry for not getting in touch with you earlier due to the accident my wife had. First of all I am pleased to see that following our telephone conversation on March 25, you acknowledge that I am the sole inventor as indicated in the revised documents attached to you E-mail.

I have just received the new version of the patent application that you sent tonight. I have had a quick look at the previous version which has generated a number of questions. I will read the new version between making preparations to move to Switzerland. It is past 9 PM now. I will read the new version as soon as possible and send you any questions I might have.

Best wishes

Ayad Abdulahad

----- Original Message -----

From: Anna_Gil@berlex.com

Date: Thursday, March 25, 2004 7:03 pm

Subject: Revised Declaration and Assignment Forms re Appln re Higher-Dose IFNB for Treatment of MS

- >
- > Privileged and Confidential Attorney Work Product
- > (Please do not copy or forward.)
- >
- >
- > Dear Ayad,
- >
- > Per our telephone discussion, attached here are the revised
- > Declaration and
- > Assignment forms. If your family name is incorrectly spelled
- > (i.e., with a
- > hyphen), please correct it in all instances that it occurs in
- > these forms.
- >
- > As mentioned in the previous email, please note that it is
- > important that
- > you first read and understand the application before signing the
- > Declaration and Assignment forms. After you have completed/signed the
- > forms, please return the originals to Mary Ann Flores via
- > overnight mail
- > (if this is problematic, please let me know asap). Please also
- > fax a copy
- > of the completed forms to Mary Ann at (510) 262-7095.
- >
- > Since this matter is of urgency, we would greatly appreciate the
- > receipt of
- > both the original and fax copy of the Declaration and Assignment
- > forms (and
- > any additional comments/revisions re the application) no later
- > than Monday,
- > 29 March 2004.
- >
- > Thank you very much for taking the time today to communicate your
- > thoughts on this matter. Please do not hesitate to contact me if
- > you have any
- > further comments/questions.
- >
- > I wish you all the very best at your new position in Switzerland.
- >

14/20

> Best regards,
> Anna
>
> (See attached file: 53208AUSM1 ASSIGN (AYAD) xxMAR04.doc) (See attached
> file: 53208AUSM1 DECPOA (AYAD) xxMAR04.doc)
>
>
>
> Anna Gil, Ph.D.
> Senior Patent Attorney
>
> BERLEX PHARMACEUTICALS
> 2600 Hilltop Drive
> P.O. Box 4099
> Richmond, CA 94804-0099
> USA
>
> Tel. No.: (510) 669-4758
> Fax. No.: (510) 262-7095
> Web Site: Berlex.com
>
> This email (and any accompanying attachments) contains information
> that may
> be confidential and privileged and is intended solely for the use
> of the
> intended recipient. Unless you are the intended recipient, please
> do not
> use, copy or disclose the contents of the email (and any accompanying
> attachments). If you have received this email (and any accompanying
> attachments) in error, please immediately notify Anna Gil at (510)
> 669-4758
> or anna_gil@berlex.com and delete this email (and any accompanying
> attachments).
>
>
>
>
>

15/20



Anna Gil

03/30/04 08:43 AM

Addressing

To: aabdulahad@optonline.net

cc:

Subject: Revised Declaration and Assignment Forms re Appln re Higher-Dose IFNB for Treatment of MS

Privileged and Confidential Attorney Work Product
(Please do not copy or forward.)

Dear Ayad,

Thank you for your reply. For clarification, I do not and did not acknowledge that you are the sole inventor by sending you a declaration and assignment form for you to sign. In fact, per our telephone conversation of 24 March 2004, I reiterated and emphasized that based on the inventorship interviews that I conducted, that you are not the sole inventor of the invention claimed in the above-identified application, and that the declaration and assignment forms could and would be revised to reflect the outcome of a determination on inventorship by Corporate Patents, based on a follow up investigation of your assertion that you are the sole inventor.

Please understand that based on the follow up investigation as to your assertion of sole inventorship, you are not the sole inventor. Thus, I will be forwarding to you a revised declaration and assignment form for your signature.

As you recall, per our telephone conversation of 24 March 2004, you informed me that you refused to sign the original declaration and assignment with the names of any other named inventors, but would only sign a declaration and assignment form with your name only. Due to your current lack of availability, your imminent departure to Switzerland on 31 March, and your refusal to sign the declaration and assignment form having any other named inventors, I revised the declaration and assignment forms to include your name, as an interim measure and only an interim measure until I had time to follow up on your assertion that you are sole inventor.

In the same telephone conversation, I also fully informed you: 1) of the importance of the accuracy of inventorship in a patent application; 2) that inaccurate inventorship could be a basis for invalidating a patent that issues from the patent application; and 3) that inventorship was based on a legal standard and necessarily determined by patent professional/attorney. I further informed you that inventorship could not be based on your rationale that you are the sole inventor because, as you asserted, members of Schering management opposed you in matters relating to your work at Berlex.

I look forward to your telephone call today as agreed. If you need further clarification on the above matter, please do not hesitate to contact me.

As mentioned in our telephone conversation yesterday, 30 March 2004, we will be filing the application by Friday, 2 April 2004, and would greatly appreciate your cooperation in this matter. Thus, please let me know of your availability today to discuss the application (if necessary), and to sign and return the executed Assignment and Declaration forms where you are not the sole inventor.

Best regards,
Anna

Anna Gil, Ph.D.
Senior Patent Attorney

BERLEX PHARMACEUTICALS
2600 Hilltop Drive

16 / 20



P.O. Box 4099
Richmond, CA 94804-0099
USA

Tel. No.: (510) 669-4758
Fax. No.: (510) 262-7095
Web Site: Berlex.com

This email (and any accompanying attachments) contains information that may be confidential and privileged and is intended solely for the use of the intended recipient. Unless you are the intended recipient, please do not use, copy or disclose the contents of the email (and any accompanying attachments). If you have received this email (and any accompanying attachments) in error, please immediately notify Anna Gil at (510) 669-4758 or anna_gil@berlex.com and delete this email (and any accompanying attachments).

17/20



aabadulahad@optonlin
e.net

03/30/04 08:52 AM

Addressing

To: Anna_Gil@berlex.com

cc:

Subject: Re: Revised Declaration and Assignment Forms re Appln re
Higher-Dose IFNB for Treatment of MS

18/20



Dear Anna,

I reiterate my position. I am the only inventor. [REDACTED]
 [REDACTED] These are the proven facts which I am not prepared to negotiate.

Ayad Abdulahad

----- Original Message -----

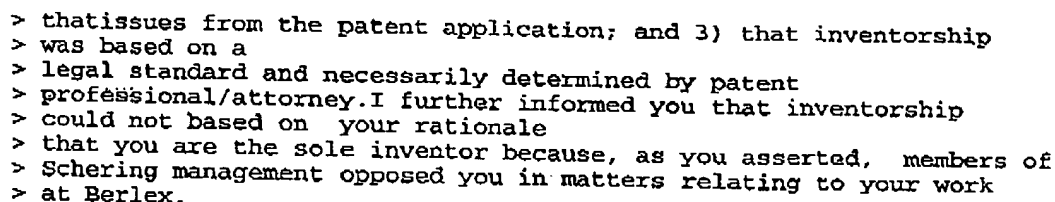
From: Anna_Gile@berlex.com

Date: Tuesday, March 30, 2004 11:43 am

Subject: Revised Declaration and Assignment Forms re Appln re Higher-Dose IFNB for Treatment of MS

>
 > Privileged and Confidential Attorney Work Product
 > (Please do not copy or forward.)
 >
 >
 > Dear Ayad,
 >
 > Thank you for your reply. For clarification, I do not and did not
 > acknowledge that you are the sole inventor by sending you a
 > declaration and
 > assignment form for you to sign. In fact, per our telephone
 > conversation of 24 March 2004, I reiterated and emphasized that
 > based on the
 > inventorship interviews that I conducted, that you are not the sole
 > inventor of the invention claimed in the above-identified
 > application, and
 > that the declaration and assignment forms could and would be
 > revised to
 > reflect the outcome of a determination on inventorship by Corporate
 > Patents, based on a follow up investigation of your assertion that
 > you are
 > the sole inventor.
 >
 > Please understand that based on the follow up investigation as to your
 > assertion of sole inventorship, you are not the sole inventor.
 > Thus, I
 > will be forwarding to you a revised declaration and assignment
 > form for
 > your signature.
 >
 > As you recall, per our telephone conversation of 24 March 2004, you
 > informed me that you refused to sign the original declaration and
 > assignment with the names of any other named inventors, but would
 > only sign
 > a declaration and assignment form with your name only. Due to your
 > current lack of availability, your imminent departure to
 > Switzerland on 31
 > March, and your refusal to sign the declaration and assignment
 > form having
 > any other named inventors, I revised the declaration and
 > assignment forms
 > to include your name, as an interim measure and only an interim
 > measure until I had time to follow up on your assertion that you
 > are sole inventor.
 >
 > In the same telephone conversation, I also fully informed you: 1)
 > of the
 > importance of the accuracy of inventorship in a patent
 > application; 2) that
 > inaccurate inventorship could be a basis for invalidating a patent

19/20



> As mentioned in our telephone conversation yesterday, 30 March
> 2004, we
> will be filing the application by Friday, 2 April 2004, and would
> greatly appreciate your cooperation in this matter. Thus, please
> let me know of
> your availability today to discuss the application (if necessary),
> and to
> sign and return the executed Assignment and Declaration forms
> where you are
> not the sole inventor.

> Anna Gil, Ph.D.
> Senior Patent Attorney
>
> BERLEX PHARMACEUTICALS
> 2600 Hilltop Drive
> P.O. Box 4099
> Richmond, CA 94804-0099
> USA

> This email (and any accompanying attachments) contains information
> that may
> be confidential and privileged and is intended solely for the use
> of the
> intended recipient. Unless you are the intended recipient, please
> do not
> use, copy or disclose the contents of the email (and any accompanying
> attachments). If you have received this email (and any accompanying
> attachments) in error, please immediately notify Anna Gil at (510)
> 669-4758
> or anna_gil@berlex.com and delete this email (and any accompanying
> attachments).

20/20

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.